DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Valcyte
Docket No.: 01E-0403

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

JAN 21 2003

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 6,083,953, filed by Syntex, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Valcyte, the human drug product claimed by the patent.

The total length of the regulatory review period for Valcyte is 2,101 days. Of this time, 1,919 days occurred during the testing phase and 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 30, 1995.

   The applicant claims July 26, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 30, 1995, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: September 29, 2000.

   The applicant claims September 28, 2000, as the date the new drug application (NDA) for Valcyte (NDA 21-304) was initially submitted. However, FDA records indicate that NDA 21-304 was submitted on September 29, 2000.

3. The date the application was approved: March 29, 2001.

   FDA has verified the applicant's claim that NDA 21-304 was approved on March 29, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: George W. Johnson
Hoffman La Roche
Patent Law Dept.
340 Kingsland Street
Nutley, NJ 07110